UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: STRYKER LFIT V40 FEMORAL HEAD PRODUCTS LIABILITY LITIGATION	*	**MDL No. 17-md-2768-IT**
This Document Relates To:	*	
All Cases	*	

PLAINTIFFS' MOTION FOR ADOPTION OF PROPOSED MODIFICATIONS TO PROTECTIVE ORDER

Plaintiffs by and through their Plaintiff Steering Committees, file this Motion for Adoption of Plaintiffs' Modifications to the Proposed Protective Order. As directed by the Court, the parties are submitting briefing on this issue simultaneously. Since the same issue is being briefed in both the federal MDL and the New Jersey MCL, to avoid duplicative briefing, this memoranda shall be submitted to both courts and thus there may be some New Jersey state court cases cited that are not applicable to the MDL briefing and federal law not necessarily applicable to New Jersey.

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I. INTRODUCTION AND SUMMARY OF RELIEF REQUESTED

The parties have met and conferred at great length in an effort to avoid burdening the courts with motion practice. The parties have agreed upon approximately 14 pages of terms of a Protective Order, but unfortunately, despite best efforts, Plaintiffs cannot agree to two extreme terms imposed by Defendants which will unduly hamper the ability of Plaintiffs to properly represent their clients as set forth below. The version acceptable to Plaintiffs is annexed as Exhibit 1 and the version proffered by Defendants with the redline markings of the Plaintiffs showing the disputed language is annexed as Exhibit 2.

This litigation is centered on medical devices designed, manufactured and sold by Defendants branded LFIT Anatomic CoCr V40 femoral heads used in conjunction with certain dissimilar metal alloy femoral stems. Plaintiffs' claims focus on the performance of the combined devices and their propensity to cause corrosion at the taper junction, ultimately leading to implant failure and serious health consequences necessitating surgical intervention to remove and replace the prosthesis and repair damaged muscle and bone.

All parties recognize this stands to be a document and expert intensive case involving experts from very discrete disciplines of medical device design, metallurgy and corrosion, tribology, materials science, orthopedics and orthopedic pathology. The parties largely agree on the form and language of the proposed protective order. However, there are two fundamental issues where an agreement could not be reached that will be summarized and then addressed in further detail below.

A. First Area of Dispute – Treating Doctors

As set forth on page 7-8, paragraph 13 (h) of the disputed Protective Order, Defendants seek to set limitations on *ex parte* communication with Plaintiffs' own doctors via a blanket

prohibition on disclosure of Confidential Discovery Material to the treating surgeons. Incredibly, the language Defendant advocates states **"at no time shall disclosure of Confidential Discovery Materials be made to a plaintiff's healthcare provider."** In the Draft order proposed by Stryker, attached as Exhibit 2, Plaintiffs struck that sentence with redline, and added the following clarifying language "[d]isclosure may be made by Plaintiff to treating physician(s) and/or healthcare provider(s) both *ex parte* and at the time depositions are conducted after the person to whom such disclosure is made has been informed of the Stipulated Protective Order of Confidentiality and has agreed in writing to be bound by it, by signing the form of acknowledgement annexed as Exhibit A."

Defendants seek to bar plaintiffs' counsels' communications with plaintiffs' doctors about anything other than plaintiffs' diagnosis, treatment and medical condition, by expressly prohibiting the disclosure and thus discussion of Confidential Discovery Materials. Plaintiffs have the burden of proof in this litigation, and therefore it is not only appropriate, but incumbent upon Plaintiffs' counsel to fully prepare their case by meeting with and calling as a witness the Plaintiffs' surgeon. The treating surgeon who implanted and/or explanted the device, and thus observed the corroded quality of the device and the damaged or necrotic surrounding tissue of the patient plaintiff, is often the best equipped to serve as the causation and defect expert in the case. By preventing the surgeon from seeing the studies, memos, adverse event reports, redesign and recall files, Defendant is trying to constrain potentially the most important witness in the case. There is no valid basis to prevent the disclosure of the key discovery data to the surgeons willing to sign the protective order. This Court should find, as MDL courts throughout this country have found time and time again, that Defendants' application to effectively limit

communications between plaintiffs' counsel and plaintiffs' own treating surgeons are improper and would impose an unreasonable burden on the Plaintiffs.

B. Second Area of Dispute - Experts

Defendants propose that if confidential information is to be shared with an expert witness (consulting or testifying) who is a consultant or "anticipated" consultant of a competitor, defined broadly as a company that designs, develops, manufactures or sells artificial joint implants, then Plaintiffs must advise Defendants of the general identification of that expert before providing him or her with the confidential information in order to provide Defendants an opportunity to move for a protective order preventing Plaintiffs from supplying such expert with necessary discovery materials produced and identified as confidential.

The actual contested language is struck out in redline in *Exhibit 2* at page 6, section 13 (b) and is quoted as follows with the non-redlined portion also included for context:

> b. Disclosure may be made to consultants or experts employed by Plaintiffs or Defendant, or their counsel to assist in the preparation and trial of this litigation. Receiving Party may not make disclosure of any Confidential Discovery Materials to any current employee, officer or director of any competitors of Supplying Party, or to anyone who, at the time of disclosure, is anticipated to become a current employee, officer or director of any competitors of Supplying Party. A "competitor" shall be defined as any medical device designer, developer, manufacturer or seller of artificial joint implants. ~~Regarding current or anticipated consultants of competitors of Supplying Party, disclosure may be made to those consultants who are not involved in the design, development, manufacturing or sale of any artificial joint implants. By way of example and not limitation, this specifically excludes those consultants who merely provide technical or scientific lectures or presentations to the public for competitors, or who merely receive funding from competitors to conduct scientific studies. In the event a Receiving Party wishes to make disclosure to any current or anticipated consultants of competitors of Supplying Party not addressed by this Order or who Receiving Party believes should be excluded from the prohibition on disclosure set forth herein, Receiving Party must provide Supplying Party in writing with information as to the general identification of the consultant to whom disclosure is to be made, without disclosing the identity of the consultant. Upon receipt of such information, Supplying Party must respond in writing within thirty (30) days as to its position on the requested disclosure. If no agreement can be reached, Receiving Party may~~

~~make a formal application to the Court for relief.~~ Under all circumstances, prior to disclosure to any consultant or expert, independent or otherwise, the individual must agree to be bound by the terms of this Stipulated Protective Order of Confidentiality by executing the acknowledgement annexed hereto as Exhibit A. A copy of each executed acknowledgement shall be maintained for Plaintiffs by Plaintiffs' Liaison Counsel, and for Defendant by Counsel for Defendant during the course of the litigation. At the conclusion of the litigation, counsel for Receiving Party shall confirm in writing with counsel for Supplying Party that it will seek to have any Confidential Discovery Materials that were provided to experts returned to counsel for the Receiving Party.

The redlined portion precludes Plaintiffs from retaining a wide variety of the most qualified experts by virtue of extending the scope to most "current or **anticipated consultants** of a competitor," in light of the way the medical device industry functions. The section prevents Plaintiffs from hiring current or "anticipated" consultants of competitors who are involved in the design, development, manufacturing or sale of any artificial joint implants.

Defendants' proposed protective order is overbroad in many respects including the fact that the definition of competitor encompasses makers of all artificial joints, thus including knees, shoulders, elbows, ankles and digits -- and thus not limited to hips. Thus, if a chosen expert was an independent academic at a university who was also a consultant to a different manufacturer on an ankle implant only, the terms of the agreement would seemingly preclude allowing her to receive documents absent disclosing certain potentially identifying information which then allows Stryker thirty days to oppose, and if so opposed, Plaintiff would have to seek permission from the court. The definition of consultant is vague and overbroad with only two discrete examples of what a consultant is not. Additionally, the proposed language of (D)(13)(b) as drafted is in effect an attempt to unilaterally limit the pool of potential experts that Plaintiffs may retain to assist in preparation and trial. Specifically, Plaintiffs object to the inclusion of the term "***anticipated***" in expanding the group of consultants to whom Receiving party "may not make disclosure of any Confidential Discovery Materials." The very nature of this litigation involves

the design, development, manufacture and testing of artificial joint implants. This undefined language is open to many interpretations in that a consultant or expert within this field might one day "anticipate" becoming a consultant for a competitor. Virtually any expert in the prosthetics field is going to have a relationship with an artificial joint implant medical device company and adopting Defendants' disclosure requirements would operate to strip Plaintiffs of their work product protection by requiring the disclosure of all or most consulting and/or testifying experts as well as limit their ability to hire the best qualified testifying experts.

Plaintiffs would suffer unfair prejudice in light of Defendant's unfettered access to experts as one of the largest medical devices companies in the world. Under Defendants' current proposed protective order, the playing field is not even remotely level, imposing unwieldy requirements on Plaintiffs in the retention of experts. The experts in the engineering fields of implant design, testing, corrosion science, tribology and metallurgy and material science as well as implant histology/pathology invariably work as industry consultants --either full time or part time in supplement to an academic career -- since the field is inherently applied. In developing implants manufacturers frequently hire a consultant engineer to do bench testing of the device or to study its materials or components. This is a niche field and there are a very limited number of laboratories, institutions or scientists that do those studies, and these material and medical device engineers do contract testing and thus are presumably "consultants" for a variety of implant manufacturers. Indeed, Plaintiffs presently have retained experts in three continents because there are so few individuals in said fields in the United States who are not consultants to Stryker already, so that plaintiffs must go across oceans to retain the most qualified experts. Nevertheless, said individuals do consult for other implant companies since that is why they are the experts and the effect of the language sought by Stryker would at a minimum result in disclosure of the experts' identities,

preclude them from seeing the key documents, burdening the court with motions and if defendant is successful in blocking the expert from seeing the documents, effectively precluding their ability to meaningfully testify at trial. Thus, the provision essentially prevents Plaintiffs from hiring those experts with the most experience in the field. If that provision is sustained, and Plaintiffs had to hire experts *not* in the specific disciplines at issue because of the overbreadth of the term consultant or anticipated consultant and the fact that those most experienced do consulting work for industry, it requires no speculation to predict that at the time of deposition and *Daubert* or *Kemp* hearings, Stryker will challenge the plaintiffs' experts credentials because they have not worked for a device manufacturer or actually designed hip implants!

II. ARGUMENT

There is no absolute privilege for withholding confidential information. Pursuant to Fed. R. Civ. P. 26(c), however, a "court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including ... requiring that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a specified way." In fact, the Supreme Court recognizes that "[t]he trial court is in the best position to weigh fairly the competing needs and interests of parties affected by discovery. The unique character of the discovery process requires that the trial court have substantial latitude to fashion protective orders." *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36 (1984) (internal citations omitted). The plain meaning of Rule 26(c) and the cases decided thereunder clearly provide that the party seeking to withhold information must bear the burden of justifying the "confidential" designation. *Pharmachemie, B.V. v. Pharmacia, Inc.*, 1998 U.S. Dist. LEXIS 2192, *9 (D. Mass. Jan. 30, 1998).

Moreover, New Jersey law highly disfavors confidentiality in court proceedings. Judge Pressler's comments to R. 1:2-1, Proceedings in Open Court notes "There are also significant policy reasons for requiring open-court proceedings deriving essentially from the common-law's aversion to and distrust of secret trials. *See, e.g., Smith v. Smith*, 379 N.J. Super. 447, 451 (Ch. Div. 2004), citing *Sheppard v. Maxwell*, 384 U.S. 333, 349-350 (1966), and *In re Oliver*, 333 U.S. 257, 268 (1948). Thus, open trials are essential to maintaining public confidence in the judicial system and fostering consistency and integrity in process and outcome. *Ibid*" PRESSLER & VERNIERO, Current N.J. COURT RULES, Comment R. 1:2-1 (GANN).

The applicable New Jersey Court Rules provision on Protective Orders R. 4:10-3 (g), allows a protective order when a "trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way." Defendant will not be able to make a showing of trade secrets for the majority of the material it will seek to seal, and while Plaintiffs are working with Defendants to have a workable protective order process to facilitate earlier document production, given New Jersey's strictures limiting protective orders, Defendants efforts in the two disputes at issue, are not grounded under New Jersey jurisprudence.

From experience with other Stryker product liability litigations, the Defendant will invariably designate as confidential most documents well beyond legitimate trade secrets, only leaving at best published studies or other publicly available documents not designated as confidential. Even though upon a court challenge many designations could be unsealed, that process is a burden on the parties and the Court and very time consuming, and it is recognized that to expedite production, defendant will likely designate most of the production as confidential thus hampering the ability to share the key discovery with experts.

A. There Is No Factual or Legal Basis To Prevent Disclosure To Treating Surgeons Willing to Sign the Protective Order

The radical language as drafted by Defendants states:

> "At no time shall disclosure of Confidential Discovery materials be made to a plaintiff's healthcare provider."

Exhibit 2. This restrictive language is contained within paragraph (D) (13) (h) page 8detailing disclosure of Confidential Discovery Material to witnesses or deponents. Thus, it is interpreted to apply specifically to Plaintiffs' potential *ex parte* communications with treating physicians, surgeons or other healthcare providers as well as at deposition or even trial.

Plaintiffs seek to exclude the language prohibiting and/or limiting substantive *ex parte* communications between plaintiffs' counsel and prescribing or treating physicians regarding the liability issues or theories, design and testing, product warnings and other germane documents produced by defendants. Plaintiffs agree that prior to disclosure of any designated confidential materials, the person to whom such disclosure is made will be informed of the Stipulated Protective Order of Confidentiality and must agree in writing to be bound by it. Plaintiffs proposed the following revision to the cited language, *supra:*

> Disclosure may be made by Plaintiff to treating physician(s) and/or healthcare provider(s) both *ex parte* and at the time depositions are conducted, after the person to whom such disclosure is made has been informed of the Stipulated Protective Order of Confidentiality and has agreed in writing to be bound by it, by signing the form of acknowledgement annexed as Exhibit A.

See Exhibit 1.

However, that assurance of the doctors signing the Protective Order is not good enough for Defendants. Instead, they seek to bar 'communications with plaintiffs' physicians and her lawyer about anything other than plaintiffs' diagnosis, treatment and medical condition, by expressly prohibiting the disclosure of Confidential Discovery Materials. In recent medical

product liability MDL's where defendants sought to prevent or limit the scope of *ex parte* meetings with plaintiffs' treating physicians to the medical condition and treatment of the plaintiff, Magistrate Judge Joel Schneider from the District of New Jersey and Judge Eldon Fallon from the Northern District of Louisiana both cited an apt analogy: "Putting a blanket restriction on every Plaintiff's attorney, which governs his or her communications with every treating physician, is akin to using a sledgehammer to crack a nut." *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 2016 U.S. Dist. LEXIS 47067, *221 (D.N.J. Apr. 6, 2016) (Attached as Exhibit 3); *In re Xarelto (Rivaroxaban) Products Liability Litigation*, MDL No. 2592, 2016 U.S. Dist. LEXIS 30822, at *6 (E.D. La. March 9, 2016) (citation omitted) (Attached as Exhibit 4). Defendants simply have not shown good cause to grant the protective order relief they request. *Younes v. 7-Eleven, Inc*., C.A. 13-3500 (RMB/JS), 2015 U.S. Dist. LEXIS 33793, at *4 (D.N.J. March 18, 2015) (denying protective order where the moving party did not show undue burden or expense) (Attached as Exhibit 5).

Judge Fallon rejected the defense argument that such *ex parte* meetings could or would unduly influence plaintiffs' physicians:

> Furthermore, physicians are learned professionals who have devoted themselves to the sciences. These individuals cannot be analogized to the cowed, reprimanded children referenced in the "woodshed" idiom. *See Carothers v. Cty. of Cook*, 808 F.3d 1140, 1149 (7th Cir. 2015) (citing *From the Horse's Mouth: Oxford Dictionary of English Idioms* 387 (John Ayto ed., 3rd ed. 2009). And to suggest that highly trained physicians would be unduly influenced by the comments of Plaintiffs' counsel fails to account for the healthy skepticism which exists between the members of these professions. The Court cannot conclude based on Defendants' sparse anecdotal evidence that physicians are a vulnerable or dishonest population. Assuming otherwise would disserve the medical profession.

Xarelto, 2015 U.S. Dist. LEXIS 33793, [WL] at *5.

Courts have long held that it is not only proper, but a matter of good advocacy for lawyers to meet *ex parte* with fact witnesses to prepare for depositions or trial. The MDL Court in *In re: Testosterone Replacement Therapy Products Liability* held, "no statute or established rule requires or even counsels in favor of these sorts of restrictions [limiting Plaintiffs' counsel's communications with treating and prescribing physicians]. *See In re: Testosterone Replacement Therapy Products Liability,* No. 1:14-md-01748 (N.D. Ill. Mar. 7, 2016), (Attached as Exhibit 6).

Thus, the *Testosterone* MDL court emphatically rejected "Woodshedding Motions", both finding that limiting the Plaintiffs' communications with their own physicians was unnecessary, unworkable, unenforceable, unfair and imposed an unreasonable burden on the Plaintiffs. *See In re: Testosterone Replacement Therapy Products Liability*; see *In re: Xarelto Products Liability Litigation*, 2:14-md-02592, 2016 U.S. Dist. LEXIS 30822 (E.D. La. Mar. 9, 2016).

Any argument by Defendants' that preclusion of *ex parte* communications, including disclosure of Confidential Discovery Materials, to Plaintiffs' treating and/or prescribing physicians is an effort to "level the playing field" is nonsensical. In particular, there is no need to "level the playing field" by restricting Plaintiffs' communications with their own doctors. For more than a decade, the Defendants have aggressively inundated physicians with information about the alleged attributes of the Stryker LFIT V40, while concealing information about its risks. Defendants' marketing and promotional materials related to their LFIT V40 hip products saturated physicians with Defendants' version of the facts. Now, after collecting millions of dollars from device sales, with no limits on what was said by its sales representatives to the surgeons, Defendants advocate Plaintiffs' attorneys should be limited in what they can provide and discuss with their own clients' doctors who would be subject in writing to the

Confidentiality acknowledgement. Clearly, in this case there is no need or basis to restrict Plaintiffs' counsel's communications.

The court in *In re Kugel Mesh,* found that the empirical evidence actually undermines that restrictions must be placed on plaintiffs' counsel's communications with physicians. There, the Magistrate Judge "reviewed four years of unregulated *ex parte* contacts between Plaintiffs' counsel and treating physicians, and concluded after evaluating Plaintiffs' alleged abuses that imposing additional restrictions would be 'unnecessary and unworkable.'" *See In re Xarelto* at 12 (citing *In re Kugel Mesh Hernia Repair Patch Litig*., 2008 WL 2420997, at *1 (D.R.I. Jan. 22, 2008).

Perhaps most apt is the analysis by Magistrate Schneider in the *Benicar* litigation, since the *Benicar* MDL also involved a parallel New Jersey state court proceeding which was being coordinated, so the issue of New Jersey's law on *ex parte* meetings with doctors was addressed. Judge Schneider's decision was similar to the *Xarelto* and *Testosterone* holdings finding it improper to constrain plaintiffs' counsel meeting with treating doctors. He also rejected that defendant's argument that two unpublished trial court decision in New Jersey were viable precedent to interfere with that basic right of plaintiffs' counsel to meet with their clients' doctors. As to the ability of defense counsel to meet with willing doctors, he noted:

> The Court acknowledges defendants can file a Stempler motion in state court if they so choose. In Stempler v. Speidell, 100 N.J. 368 (1985), the New Jersey Supreme Court authorized the defendant to communicate with the decedent-plaintiff's treating physicians subject to certain conditions, but only with respect to matters relating to the litigation. Nevertheless, the Supreme Court was careful to point out that trial courts have flexibility "to fashion appropriate procedures in unusual cases without interfering unnecessarily with the use of personal interviews in routine cases." Id. at 383. These are certainly not routine cases. See Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical, 372 N.J. Super. 105, 136 (Law Div. 2003)(denying Stempler authorizations in a mass tort case). Thus, there is no guarantee if defendants file a Stempler motion in state court it will be granted.

Moreover, Judge Schneider noted that as to what the Plaintiffs' counsel can disseminate to others "[d]efendants should take some comfort in the fact that the persons to whom plaintiff can show defendants' "Protected Information" is limited. (Exhibit 4). See Stipulated Discovery Protective Order [Doc. No. 46]; That order, attached hereto as Exhibit 7, and available at http://www.njd.uscourts.gov/sites/njd/files/DiscProtOrd.pdf provides in paragraph 20 (g) that "In no event shall a Receiving Party make disclosure to consultants/experts who are employees, officers or directors of any competitor of Defendants or who at the time of disclosure is anticipated to become an employee, officer, or director of any competitor of Defendants…" This is very similar to what plaintiffs' have agreed to here – preventing disclosure to employees, officers or directors of a competitor. Stryker's extreme effort to expand that to a consultant or anticipated consultant of a competitor is extreme and wrong on many levels.

B. Plaintiffs Should Be Able to Communicate With and Share Documents with Plaintiffs' Doctors Who Are in Constant Contact With the Defendants' Sales Force

To the extent Defendants argue they have included provision (D)(13)(h) in their proposed Protective Order to "level the playing field", Plaintiffs note these Defendants have had extensive access to and relationships with these Plaintiffs' physicians and healthcare providers through their marketing and surgeon training efforts, which in many cases continues to date. Through their marketing and training representatives, Defendants have had the unfettered opportunity to provide these doctors with information about these products "*ex parte"* such that "[a]s a practical matter, the Defendants already have information, including documentation, regarding what its representatives told the treating physicians about [the subject devices]". *In re Vioxx Products Liability Litigation*, 230 F.R.D. 473 (E.D. La. 2005).

The Plaintiffs' surgeons and/or healthcare provider(s) are key fact witnesses beyond their knowledge of Plaintiffs' medical conditions and should be able to learn from internal documents the truth about the product design and defects, and problems observed by other doctors in reports to the company, especially in light of the barrage of marketing from defendants. It surprises many Plaintiffs to learn that their surgeons typically allowed the sales representative for Stryker to be present during their surgeries. As stated by a recent study by O'Connor et. al. of Brown University Medical School "[m]edical device representatives ("device reps") have become an integral part of operating room personnel." *Salespeople in the Surgical Suite: Relationships between Surgeons and Medical Device Representatives*, **PLOS One**. 2016; 11(8), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4972437/, (Attached as Exhibit 8). In fact, as noted in the same study:

> Device rep input into a surgeon's implantable device choices is especially relevant in the context of the FDA 510(k) device approval category, which allows devices deemed to have "substantial equivalence" to already marketed products to be implanted into humans without clinical testing. 510(k) approval enables the manufacturer to circumvent the more stringent premarket proofs of safety and efficacy required of new devices. Lack of such proofs, coupled with aggressive marketing and early adoption of 510(k) devices, can sometimes lead to unexpected and dramatic failures, for example, when certain metal-on-metal total hip replacement systems failed, causing chronic pain and disability and the need for revision surgery. These devices were removed from the market—after 500,000 had been implanted.
>
> The financial connections between the device industry and surgeons are widespread and substantial and may contribute to a surgeon's reliance on industry product claims. The literature abounds with reports documenting the extent to which surgeons receive payments from industry—more than half of all surgeons, with orthopedists leading with respect both to the number receiving payments and the amount of money received.

In light of the ubiquitous presence of Stryker reps in the operating rooms of the plaintiffs' surgeons, and their contacts outside of the operating room, Defendants should be precluded from seeking to prevent Plaintiffs' counsel from showing the surgeons the discovery data that likely

contradicts the constant marketing pitch of safety and efficacy they have encountered over the years.

Plaintiffs should not be limited in discussing with treating physicians whether the frequency and severity of complications they experienced are consistent with the information they were provided by the Defendants – and information known to Defendants that may not have been provided to the doctors.

Further, Plaintiffs should not be limited in their ability to address the Defendants' failure to warn, in that Plaintiffs' surgeons are the critical fact witnesses. Under the learned intermediary doctrine, which is applied in the majority of states, including Massachusetts and New Jersey, the Defendants will likely contend that their duty to warn ran to the doctor (the "learned intermediary") instead of to the patient. What the doctor was told – or *not told* – by the Defendants in light of the Defendants' knowledge at the time are vitally important issues of fact. As set forth in *In re: Avandia Marketing, Sales Practices and Prods. Liab. Litig.*, "the adequacy of a warning [under several states' laws' is determined based on what a manufacturer knew or should have known about a given risk at the time a patient is prescribed the drug or the cause of action arose, and whether the label warned of that risk. A manufacturer is not excused if it remains purposefully ignoring of a particular risk. The duty to warn is thus a continuing one, and obligates a manufacturer to conduct research and otherwise investigate risks associated with its products, and then update warnings as appropriate." 817 F. Supp. 2d 535, 547 (E.D. Pa. 2011).

What the particular plaintiff's surgeon would have done had he or she known all information known to the Defendants (including whether or not he or she would have implanted the product, given such information) are necessary inquiries in these cases. The only way for Plaintiffs to address these issues in preparation is to show the doctors the information from

discovery not shared by the sales reps to ascertain if that information would have altered the choice of device and treatment of the patient. It is entirely appropriate, indeed necessary, for Plaintiffs to address these important questions with Plaintiffs' treating physicians in preparing these cases.

C. Most MDL Decisions Reject the Limits Advocated by Stryker as Unnecessary, Unfair and Unreasonably Burdensome

The seminal federal MDL decision was issued more than a decade ago in the *In re Vioxx Products Liability Litigation,* 230 F.R.D. 473 (E.D. La. 2005) recognizing the importance of the Plaintiffs' counsel ability to meet with the clients' doctors. Judge Fallon cited "the time-honored doctor-patient confidential relationship which has been recognized and protected in both Western and Eastern civilization for over 2000 years." *Id*. at 476

Since the *Vioxx* decision courts considering this issue have time and time again rejected defense motions to prohibit or restrict plaintiffs' counsel's communications with plaintiffs' physicians. See e.g., *In re: Xarelto Products Liability Litigation*, 2:14-md-02592, 2016 U.S. Dist. LEXIS 30822 (E.D. La. Mar. 9, 2016); *In re: Testosterone Replacement Therapy Products Liability*, No. 1:14-md-0 (N.D. Ill. Mar. 7, 2016); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig*., No. 08-md-2004, slip op. at 2 (M.D. Ga. May 28, 2015) (Attached as Exhibit 9); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig*, No. 12-md-2327, 2015 U.S. Dist. LEXIS 139926 (S.D. W.Va. Oct. 13, 2015); *In re: E.I. DuPont de Nemours and Co. C-8 Personal Injury Litig*., No. 2:13-md-2433, at 3-4 (S.D. Ohio May 16, 2014) (Attached as Exhibit 10); *In re Levaquin Prods. Liab. Litig,* No. 08-md-1943, 2012 U.S. Dist. LEXIS 116088 (D. Minn. Aug. 17, 2012); *In re: C.R. Bard Inc., Pelvic Repair Sys. Prods. Liab. Litig.,* No. 10-md-2187, slip op. (S.D. W. Va. Aug. 3, 2012) (Attached as Exhibit 11); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices and Prods. Liab. Litig.*, 09-md-2100, 2011 U.S. Dist. WL

996549 (S.D. Ill. Mar. 4, 2011); *In re Nuvaring Prods. Liab. Litig*., No. 4:08-md-1964, 2009 WL 77542 at *1 (E.D. Miss, Mar. 20, 2009) (Attached as Exhibit 12); *In re Kugel Mesh Hernia Repair Patch Litig.,* 2008 WL 2420997, at *1 (D.R.I. Jan. 22, 2008*).*

These courts have reasoned that the requested restrictions were unnecessary, unworkable, unenforceable, unfair, and imposed an unreasonable burden on the Plaintiffs. The court in the *Ethicon Mesh MDL* acknowledged there are some disadvantages in only allowing one party to have *ex parte* communications with a witness, but the court observed that "placing a blanket restriction on every Plaintiff's attorney, which governs his or her communications with every treating physicians, is akin to using a sledgehammer to crack a nut." *In re Ethicon, Inc.* 2015 U.S. Dist. LEXIS 139926, at 3287. The Ethicon court explained:

> [T]here are disparities in every litigation. The court is hard-pressed to construct a completely level playing field. Moreover, attorneys, as officers of the court, have ethical rules that they must follow, which include a prohibition on improperly influencing witnesses. The court must presume that attorneys will abide by heir ethical obligations; when they do not, there are sanctions that can be imposed to address the specific malfeasance.

These cases are analogous to the case at hand, and this Court should hold that Plaintiffs' counsels' communications, including the disclosure of Confidential Discovery Materials subject to Stipulated Protective Order, with the Plaintiffs' own physicians should not be restricted.

D. The Identity of Consulting Experts is Non-Discoverable

The work-product doctrine protects "documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's attorney, consultant, surety, indemnitor, insurer, or agent)." Fed. R. Civ. P. 26(b)(3)(A). As a part of work product immunity, a party cannot obtain discovery of "facts known or opinions held by an expert who has been retained or specially employed by another party in anticipation of litigation or to prepare for trial." Fed. R. Civ. P. 26(b)(4)(B). Absent

special circumstances, a party cannot even obtain discovery of the name of the consulting expert. *See Hoover v. U.S. Dept. of the Interior*, 611 F.2d 1132, 1142 n. 13 (5th Cir.1980) (holding that a "party seeking disclosure under Rule 26(b)(4)(B) carries a heavy burden"); see also *Ager v. Jane C. Stormont Hasp. & Training Sch. for Nurses*, 622 F.2d 496, 502 (10th Cir. 1980) (holding that "the identity, and other collateral information concerning an expert who is retained or specially employed in anticipation of litigation, but not expected to be called as a witness at trial, is not discoverable" absent special circumstances).

Rule 26(b)(4)(D)(ii) bars discovery and the deposition of consulting experts except in "exceptional circumstances under which it is impracticable for the party to obtain facts or opinions on the same subject by other means." The rationale for this Rule, as discussed in the Rule 26 Advisory Committee Notes and the case law, is that the primary purpose of Rule 26(b)(4)(A), which permits discovery from testifying experts, is "to permit the opposing party to prepare an effective cross-examination." *See Hoover v. United States Dep't of the Interior*, 611 F.2d 1132, 1142 (5th Cir. 1980).

Similarly under New Jersey law which in this context was expressly modeled after FRCP 26(b)(4)(B), "[a]bsent exceptional circumstances, our Rules of Civil Procedure do not permit discovery of the names or opinions of experts that a party has consulted but does not intend to call at trial. See R. 4:10-2(d)(3)." *Graham v. Gielchinsky*, 126 N.J. 361 (1991). The standard for ascertaining exceptional circumstances is one where "it is impractical for the party seeking discovery to obtain facts or opinions on the same subject by other means." PRESSLER & VERNIERO, Current N.J. COURT RULES, Comment R. 4:10-2[5.4] (GANN). Thus, the terms proposed conflict with the New Jersey court rules since the scenario in the Defendant's proposed order clashes with that limited exception.

Ultimately, Defendants' proposal is time consuming and unnecessary. Under the forms of the protective orders proposed by both sides, all persons or entities receiving confidential information will be required to sign and abide by the terms of the protective order. Both sides acknowledge that all individuals involved in this case will be required to acknowledge the requirements of this Court's order. The requirement that anyone who receives confidential information will have to sign the acknowledgment to the protective order will provide Defendants with adequate protection without destroying the ability of Plaintiffs to retain experts and consultants free from the interference of their adversaries.

Requiring a party to receive "approval" from its opponent before consulting with experts is inconsistent with the Federal Rules of Civil Procedure and inconsistent with the adversarial nature of our system. If a party could simply and successfully object to its opponent's choice of a retained expert, it would stifle a party's ability to prepare and present its case. If an opposing party may learn the identity and expertise of an adversary's retained consultants, it would diminish the work-product doctrine by needlessly encumbering an attorney's ability to access and evaluate complex cases. Defendants' proposed order fosters neither the timely nor reasonable resolution of the parties' dispute.

III. CONCLUSION

Defendants have proposed a drastic revision of the rules concerning the disclosure of consulting experts, the ability to retain experts and the ability to conduct substantive *ex parte* communications between Plaintiffs' counsel and treating doctors. Plaintiffs recognize that confidential material will be exchanged in this case and Plaintiffs are willing to accept a reasonable protective order to safeguard that information. Defendants' insistence on the two disputed sections is unreasonable. Plaintiffs' proposal protects the confidential information

Defendants may tender in discovery but it does not provide Defendants with the lopsided advantage of ascertaining Plaintiffs expert selection process, unilaterally limiting the potential pool of qualified consulting and/or testifying experts and prevent Plaintiffs' surgeons, potentially the most critical witness in the case, from learning the material discovered. Therefore, Plaintiffs request that this Court enter the Protective Order which Plaintiffs propose.

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Respectfully submitted,

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